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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/046,575	01/16/2002	Nishizumi Nishimuta	018995-452	4939

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Platon N. Mandros  
BURNS, DOANE, SWECKER & MATHIS, L.L.P.  
P.O. Box 1404  
Alexandria, VA 22313-1404

EXAMINER

FAY, ZOHREH A

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 05/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/046,575

Applicant(s)

NISHIMUTA ET AL.

Examiner

Zohreh Fay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 17-31 is/are pending in the application.
- 4a) Of the above claim(s) 4,5,7,8,15 and 17-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,6,9-14 and 31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

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Claims 1-15 and 17-31 are pending.

Claims 4-8 and 15 and 17-30 are withdrawn from the concentration.

The elected claims 1-3, 6, 9-14 and 31 are presented for examination.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3, 6, 9-14 are rejected under 35 U.S.C. 103 as being unpatentable over Goodman et al. (WO 98/27960) in view of Fleischer (1999, abstract only); or Fleischer (1999) and Miller et al. (1980, abstract only).

Goodman et al. Teach a viscous hydrogel composition containing nitroimidazole (e.g. tinidazole) for treating inflamed skin diseases such as rosacea and eczema, see the abstract and page 1, lines 12-15, especially example 1. The exemplified species, tinidazole in a therapeutically effective amount about 0.75% is well taught and encompassed by scope of the claims.

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Applicant's claims differ from WO Patent because they specifically require treatment of atopic dermatitis.

However it would have been obvious to a person skilled in the art at the time the invention was made to substitute the inflamed skin diseases of (WO'960) with atopic dermatitis when WO'960 is taken in view of Fleischer (1999); or Fleischer and Miller (1980) together because later references, teach deficiencies found in Goodman et al's teaching.

Firstly, Fleischer teaches that atopic dermatitis is a form of eczema (i.e. a chronic and relapsing form of eczema, see the entire abstract.

Secondly, Fleischer also teaches that immune regulation plays an important role in the cause of atopic dermatitis and therefore, immunosuppressants are effectively used in the treatment of atopic dermatitis. Miller teaches that tinidazole is effective immunosuppressant in vivo, see abstract.

Thus, one would have been motivated to prophylactically treat atopic dermatitis using tinidazole because treating eczema could prevent further undesirable implications (e.g. relapsing or transforming into chronic eczema) which can become atopic dermatitis, considering that tinidazole is proven to be an effective therapeutic modality for eczema or other inflamed skin diseases. If immune regulation is considered to be the underlying mechanism of atopic dermatitis, one would have been motivated to make such substitution with assurance and reasonable expectation of success, considering that Miller teaches that tinidazole as an effective immunosuppressant in vivo.

One would have been motivated to do so, with the reasonable expectation of success, because it is considered to be desirable to have extended therapeutic modalities to improve patient compliance by enhancing patient satisfaction and increasing the selection option.

These references are particularly pertinent and relevant because all the claimed species and their roles are well taught in the cited references when they are combined together. Thus one would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities<sup>0</sup>, and pertinent to the problem which applicant concerns about. See MPEP 2141.01(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Fay whose telephone number is (571) 272-0573. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z.F

ZOHREH FAY  
PRIMARY EXAMINER  
GROUP 1200

